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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,260	06/30/2005	Jeffry D Watkins	X-16758M	5377

25885 7590 10/09/2007  
ELI LILLY & COMPANY  
PATENT DIVISION  
P.O. BOX 6288  
INDIANAPOLIS, IN 46206-6288

EXAMINER
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SKELDING, ZACHARY S

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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10/09/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p align="center">10/541,260</p>	<p>Applicant(s)</p> <p align="center">WATKINS ET AL.</p>	
	<p>Examiner</p> <p align="center">Zachary Skelding</p>	<p>Art Unit</p> <p align="center">1644</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/> Paper No(s)/Mail Date ____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/> Paper No(s)/Mail Date. ____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: ____.</p> |
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### DETAILED ACTION

1. Claims 1-24 are pending.

#### Restriction Requirement

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims will be restricted.

Group I. Claims 2-4 drawn to a composition comprising the polypeptides of SEQ ID NOs: 15, 25 and 33 and 37, 45 and 53 OR SEQ ID NOs: 15, 25 and 33 and 39, 45 and 53.

Group II. Claims 5 and 6, drawn to a composition comprising the polypeptides of SEQ ID NOs: 13, 27 and 33 and 37, 55 and 53.

Group III. Claims 9-14, drawn to a composition comprising a TNF- $\alpha$  binding, or a nucleic acid sequence encoding a TNF- $\alpha$  binding molecule.

Group IV. Claims 15-21, drawn to a method of treating a TNF- $\alpha$  mediated disease.

Group V. Claims 22-24, drawn to a composition comprising the polypeptides of SEQ ID NOs: 93, 95, 97, 87, 89 and 91.

4. Claims 1, 7 and 8 link Groups I and II.

The restriction requirement between Groups I and II is subject to the nonallowance of the linking claim(s), claims 1, 7 and 8.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a

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restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups III and IV, for example, were found to have no special technical feature that defined the contribution over the prior art of Salfeld et al. (U.S. Patent No. 6,258,562, cited by applicant on their IDS of June 30, 2005).

Salfeld teaches TNF- $\alpha$  binding molecules, such as the D2E7 IgG4 antibody, which neutralize TNF $\alpha$  in a cell based assay with an EC50 of  $2.0 \times 10^{-11}$  or less, as well as methods of treating a TNF- $\alpha$  mediated disease with said antibodies (see, in particular, Column 37, Table 7 and the paragraph bridging columns 4-5).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.
- If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.
- Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.  
Patent Examiner  
September 26, 2007



MICHAEL BELYAVSKIY, PH.D.  
PATENT EXAMINER

27/09/07